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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/936,922	10/31/2001	Meir Shinitzky	110598	3023

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EXAMINER

WANG, SHENGJUN

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 12/03/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/936,922

Applicant(s)

SHINITZKY, MEIR

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 September 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-36 is/are pending in the application.
- 4a) Of the above claim(s) 7 and 21-24 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6, 8-20 and 25-36 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 9.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

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DETAILED ACTION

Upon reconsideration the restriction requirement set forth in the prior office action is withdrawn and the species election requirement is maintained.

1. Claims 7, 15, 21-24, and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 12 submitted September 13, 2002.
2. Applicant's election with traverse of compound 1, and schizophrenia in Paper No. 10 is acknowledged. The traversal is on the ground(s) that the species are within a generic claims. This is not found persuasive because if the species are distinct from each other, a species election requirement for search purpose is proper.
3. The requirement is still deemed proper and is therefore made FINAL.
4. The claims have been examined insofar as they read on elected species.

Claim Objections

5. Claims 8, 16, 18 and 26 are objected to because of the following informalities: either full chemical names or the abbreviations may be used for compounds, but not both. Appropriate correction is required.

Claim Rejections 35 U.S.C. 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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7. Claims 3-6, 8, 18-20, 25-26 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treatment of the disorders or diseases herein, does not reasonably provide enablement for prevention of the diseases or disorders, or prevention of neuro-degeneration. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The claims are directed to preventing dementia or neuro-degeneration, particularly, prevention of schizophrenia. However, the specification fails to adequately teach how to use the method to prevent dementia or neuro-degeneration. Particularly, etiologies of dementia or neurodegeneration have not been completely understood in the art. No known method has been developed for preventing the occurrence of dementia or neuro-degeneration. See, Merck Index, pages 1336-1339. For Schizophrenia, a psychiatric disorder, also a form of dementia, the etiology may link to inherited. See, Merck Index, pages 1532-1537. There is no evidence in the art that a pharmaceutical agent may be successful in preventing an inherited disease. The current known treatment of such disorders is limited to symptomatic treatment. Thus, it is clear from the evidence of Parish et al. and van Oosten et al. that the ability to treat and or prevent multiple sclerosis is highly unpredictable and has met with very little success. Applicants have not provided any convincing evidence that their claimed invention is indeed useful as preventive for dementia, and for schizophrenia in particular, and have not provided sufficient guidance to allow one skilled in the art to practice the claimed invention without undue experimentation. In the absence of such guidance and evidence, the specification fails to provide an enabling disclosure.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 3-36 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claims 9-16 and 27-36 provides for the use of phosphorus heterocyclic compounds, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claims 9-16 and 27-36 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

Claim 5 recites mental disorders or diseases consisting two subgenus: dementia mental disorders and neuro-degenerative disorders. Note the two subgenus herein claimed are not mutually exclusive. E.g., a dementia mental disorder may also be a neuro-degenerative disorder, such as Alzheimer's disease. The claim is indefinite as to the scope of each subgenus encompassed thereby.

Claim 6 recited a mental disorder is one of two subgenus: schizophrenia or dementia. Note the two subgenus herein claimed are not mutually exclusive. Particularly, schizophrenia is a dementia. The claim is indefinite as to the scope of each subgenus encompassed thereby.

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11. Claim 20 recites the limitation "schizophrenia" in line 2. There is insufficient antecedent basis for this limitation in the claim. Particularly, claim 18 defines the disorder as other than dementia. Schizophrenia is a dementia.

Claim Rejections 35 U.S.C. 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

13. Claims 1-8, 17-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Chun et al. (US 6,125,345), in view of Piazza et al. (IDS, AA), Kobayashi et al. (IDS, AG-AJ).

14. Chun et al. teaches a method of promoting the survival of myelin producing cell, and treating neuro-disorders including Alzheimer's disease, by employing LPA receptor agonist. See, particularly, column 5, lines 3-37; column 6, lines 37 bridging column 8, line 30.

Chun et al. does not teach expressly the employment of cyclic phosphate, e.g., acyl 1,2 glycerophosphate, for treating schizophrenia.

However, Piazza or Kobayashi et al. teaches that acyl 1,2 glycerophosphates are similarly useful as LPA, and are known to be useful for treating dementia. See, particularly, the abstract and column 2, lines 22 bridging column 4, line 6 in Piazza, and the abstracts of AI and AJ.

Therefore, it would have been prima facie obvious to a person of ordinary skill in the art, at the time the claimed invention was made, to employ acyl cyclic phosphate for treating schizophrenia, a form of dementia.

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A person of ordinary skill in the art would have been motivated to remove employ acyl cyclic phosphate for treating schizophrenia, a form of dementia because acyl cyclic phosphate are known to be similarly useful as LPA, and are particularly useful for treating dementia. A agents known generally for treating dementia would have reasonably been expected to be useful for treating any dementia, including schizophrenia.

Allowable Subject Matters

Method of employing 1,3 cyclic glycerophosphate for treating schizophrenia is allowable since prior art do not teach or fairly suggested the employment of 1,3 cyclic glycerophosphate for treating such disorder.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (703) 308-4554. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Examiner



Shengjun Wang

November 26, 2002